Linda J. Clark
Joseph A. Murphy
Hiscock & Barclay, LLP
80 State Street
Albany, New York 12207-2543
Telephone: (518) 429-4241/4248
lclark@hblaw.com
jmurphy@hblaw.com

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA.

Plaintiff,

vs.

NARCO FREEDOM, INC.

Defendant.

Case No. 14-CV-8593

Hon. John G. Koeltl, U.S.D.J.

POST-HEARING MEMORANDUM OF LAW IN OPPOSITION TO APPLICATION FOR A PRELIMINARY INJUNCTION

HISCOCK & BARCLAY, LLP
Attorneys for Defendant
Narco Freedom, Inc.
80 State Street
Albany, New York 12207
Telephone: (518) 429-4241

Linda J. Clark, Esq.
Joseph A. Murphy, Esq.

Of Counsel

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PRELIMINARY STATEMENT

Defendant Narco Freedom, Inc. ("Defendant" or "Narco Freedom") submits this post-hearing memorandum of law in further opposition to the application by Plaintiff United States of America ("Plaintiff" or "Government") for a preliminary injunction.

The Government's motion should be denied for numerous reasons. First, its proposed relief would displace existing State regulatory schemes and destroy a treatment-with-housing model the currently fills an acute gap in social needs of individuals needing substance abuse treatment who also lack housing.

The Government's motion also fails under a plain application of the relevant statutes. Under a 2010 amendment to the Affordable Care Act that added an exception to the definition of remuneration applicable to the Anti Kickback Statute, and Narco Freedom's treatment-with-housing model does not constituted remuneration, and in any event is not an improper inducement or kickback. As revealed at hearing and explained below, Narco Freedom's provision of housing as an adjunct to its substance abuse treatment "promotes access to care and poses a low risk of harm to patient and Federal health care programs." Expert testimony demonstrated that Narco Freedom's treatment-with-housing model promotes access to care by giving clients the housing stability they need in order to attend treatment programs and focus on the difficult work of achieving sobriety. Evidence presented at the hearing also established that Narco Freedom's model poses low-to-no risk of harm to its patients and in fact results in improved outcomes over models that do not provide housing with treatment. Similarly, Narco Freedom's model poses low-to-no risk of harm to Medicaid or other federal health care

programs and, to the contrary, results in savings in the form of better clinical outcomes and less recidivism.

As set forth below, the Government has simply not met its burden under the injunction standard, nor has it justified the inequities of the broad injunctive relief it seeks.

STATEMENT OF FACTS

Narco Freedom is a provider of substance abuse treatment services. It operates several programs, many of which have nothing to do with housing. Bethea Decl. ¶¶ 7-8; Tr. 413:8-21 (G. Bethea). In recognition of the latest evidence from the field of substance abuse treatment, Narco Freedom has adopted an integrated model of treatment, including access to an array of services, including housing. The housing services are offered only to patients who are (1) referred for treatment by other providers, and (2) approved and assessed by Narco Freedom's clinical staff as being eligible for such treatment under applicable outpatient guidelines. Essentially, it is a treatment-first model. Tr. 433:20–434:3 (G. Bethea); Def. Ex. AC.

Some such referrals are mandatory orders from the Department of Parole pursuant to state law, which requires parolees to establish a residence at the time they are released for treatment. *See, e.g.*, Def. Ex. A. at 1 ("You must report directly to the Program upon arrival in City. . . . Agency: Freedom House . . . Contact: Intake"); *id.* at 3 ("RESIDENCE: Narco Freedom – Halfway House"). This is not an unusual circumstance, as the parolee frequently exhibits co-morbidities of substance abuse with housing instability. Tr. at 152 (T. Herzog).

Equally as important, Narco Freedom does not rely solely upon the DOCCs assessment that treatment is required. Narco Freedom's clinical staff first conduct their own assessment to confirm whether a patient qualifies for outpatient substance abuse treatment under the clinical guidelines. Only then will Narco Freedom confirm availability of housing for that individual.

Tr. 417:6-8; 432:24–433:2 (G. Bethea); Def. Ex. AC (Patient "is to report to our primary intake office . . . . After her evaluation and if the participant is undomiciled, upon a request from DOCCS we will place her in our transitional housing residence which will be Freedom 4"). Narco Freedom is required to perform this assessment of the patient's need for clinical services and housing. *See* Def. Ex. E, OASAS-approved Intake Form; Tr. 264:8-9 (K. Greene).

Once the Narco Freedom clinical assessment determines that the patient is in need of housing, he or she is referred to a Freedom House to secure housing. Tr. 417:6-8; 432:24–433:2 (G. Bethea). There are necessary exceptions to address travel logistics, such as when parolees arrive after the Intake office is closed, such as when parolees leave from upstate late in the day or on weekends. Tr. 386-87 (D. DiCicco). Narco Freedom then provides a bed for the night, and the patient spends the night as a guest. Other times a patient may go to a Freedom House first simply to drop off belongings. Tr. 369-70 (D. DiCicco). The next morning (or as soon thereafter as possible), the patient proceeds to Narco Freedom's clinical intake process.

Once in the Freedom House as a resident and patient at Narco Freedom's outpatient program, the patient is provided with temporary accommodations in an independent living environment, not an institutional one. Tr. 415:19-22 (G. Bethea). Patients are asked to follow rules designed to minimize open drug use and encourage good behavior. Tr. 440:24–441:20 (G. Bethea); Def. Ex. AV. The houses are not, however, secured institutional residences, and residents maintain a large degree of independence and freedom. As described in greater detail below, this provision of housing is a critical aspect of the treatment program. Without it, the current scientific evidence shows that the efficacy of treatment drops precipitously.

ARGUMENT

LEGAL STANDARD FOR PRELIMINARY INJUNCTION

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 24 (2008). When the Government seeks injunctive relief pursuant to 18 U.S.C. § 1345, it is required, among other things, to "demonstrate that 'probable cause' exists to believe that the defendant is currently engaged or about to engage in a fraudulent scheme" violative of an applicable statute. *See United States v. William Savran & Assoc.*, 755 F. Supp. 1165, 1177 (E.D.N.Y. 1991).

Moreover, "[i]njunctive relief is authorized under section 1345 only when the alleged fraudulent scheme is ongoing and there exists a threat of continued perpetration; the statutory equitable remedy is not available for solely past violations." *Id.* at 1178. While "a showing that a scheme has been carried out in the past, even in the recent past, is relevant to the determination of the probability that such a scheme will be perpetrated in the future," such a showing "is not dispositive when other circumstances indicate that there is little danger that the scheme will continue into the future." *United States v. Belden*, 714 F. Supp. 42, 45-46 (N.D.N.Y. 1987)

Additionally, while some courts have held that the Government is relieved of having to prove the traditional element of irreparable harm to obtain an injunction under § 1345 (*see, e.g., Savran*, 755 F. Supp. at 1178-79), it is still proper and necessary for the court to consider other elements traditionally relevant to an application for injunctive relief – including, importantly, a balancing of the equities and relative hardships of both the parties and non-parties. *See, e.g., SEC v. Management Dynamics, Inc.*, 515 F.2d 801, 808 (2d Cir. 1975).

Here the Government has failed to meet its burden on each of those elements to obtain injunctive relief.

I. THE GOVERNMENT HAS NOT MET ITS BURDEN OF ESTABLISHING A LIKELIHOOD OF SUCCESS ON THE MERITS

The Government has not met its burden of showing that probable cause exists to believe that Narco Freedom is currently engaged or about to engage in a fraudulent scheme" violative of an applicable statute. To the contrary, at hearing Narco Freedom has shown (although it is not its burden to show) that its treatment-with-housing model does not constitute a violation of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) ("AKS").

A. An Amendment to the Affordable Care Act added an exception to the definition of remuneration applicable to the Anti Kickback Statute

To prove a violation of the Anti-Kickback Statute, the government must establish that the defendant (1) knowingly and willfully (2) gave, received, or solicited a remuneration (3) in return for patient referrals (or other business) (4) in connection with a federal health care program. On the record before the Court, this burden has not been met for purposes of evaluating the request for immediate and expansive injunctive relief.

Traditionally, the AKS has been strictly construed, creating concern among providers regarding how the potential breadth and vagaries of the statute could impact the provision of services that are clinically beneficial. *See* Dept. of Health and Human Svcs. Office of Inspector Gen., 79 Fed. Reg. 59717, 59718 (proposed Oct. 3, 2014). In response to this concern, the Patient Protection and Affordable Care Act ("ACA" or the "Act") signed into law in March 2010 included a number of important fraud and abuse provisions, including changes to the Federal Health Care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"). *See* Section 6402(d)(2)(B) of the ACA entitled "Clarification of Treatment of Certain Charitable and Other Innocuous Programs." The goal of the ACA's exception is encouraging better care and better health at lower cost through innovative means, some of which could involve providing incentives to beneficiaries. *See generally*, C.F.R. Vol. 79, Issue 92 (Oct. 3, 2014). The Act modified the definition of "remuneration" under the AKS with regard to the prohibition on beneficiary

inducements such that as of March 23, 2010, "remuneration" no longer includes "remuneration which promotes access to care and poses a low risk of harm to patient and Federal health care programs." *See* 42 U.S.C. 1320a-7a(i)(6)(F).

While this ACA-mandated exception to the definition of "remuneration" was added to 42 U.S.C. 1320a-7a, which is the civil monetary penalties law ("CMP Law") of the Social Security Act ("SSA"), it also applies to the AKS. The CMP Law and AKS are both part of the SSA, and the CMP Law is the AKS's civil counterpart.

The amended definition of "remuneration" applies here because the AKS derives its definition of the term "remuneration" from 42 U.S.C. 1320a-7a(i)(6), as amended. *See* 42 U.S.C. § 1320a-7b(b)(2)(B). The term "remuneration" is not exclusively defined in the AKS, and there is no catch-all definition of "remuneration" in 42 U.S.C. § 1320a-7b. Courts therefore have looked to the definition of "remuneration" in 42 U.S.C. § 1320a-7a(i)(6) when analyzing the scope of that term. *See, e.g., U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc.*, No. 05 Civ. 5393 (RPP), 2011 U.S. Dist. LEXIS 37014, at *2 (S.D.N.Y. Apr. 5, 2011), aff'd sub nom., *United States v. Quest Diagnostics Inc.*, 734 F.3d 154 (2d Cir. 2013) (The AKS defines "remuneration" as including "transfers of items or services for free or for other than fair market value.") quoting 42 U.S.C. § 1320a-7a(i)(6). As such, the exceptions inserted at 1128A(i)(6) of the CMP Law apply to what is and is not considered prohibited remuneration under the AKS.[1]

[1] The CMP Law provides for a civil monetary penalty for certain inducements offered to Medicare and Medicaid beneficiaries. *See* 42 U.S.C. 1320a-7a(5). The ACA-mandated exceptions to the term "remuneration" were added for purposes of the beneficiary inducement provisions. *See* OIG Advisory Opinion 11-01 (issued Jan. 3, 2011, posted Jan. 10, 2011) (acknowledging new ACA exceptions and noting that inducement prohibition does not apply to

B. Narco Freedom's treatment-with-housing model is not remuneration because it improves access to care with minimal risk as compared to the alternative of homelessness

Narco Freedom's provision of housing is an example of a non-clinical service that is a proper – and protected - adjunct to treatment as part of an integrated service model that is a best practice under modern treatment standards. It is precisely this type of client-centered integrative service model that the ACA seeks to promote through its explicit relaxing of doctrinal approaches to pre-existing laws, like the anti-kickback statutes. *See* Dept. of Health and Human Svcs. Office of Inspector Gen. 79 Fed. Reg. 59717, 59726 (proposed Oct. 3, 2014). This relatively minor financial subsidy of a patient's inadequate state housing subsidy should not be banned at this procedural juncture, on the current record, pursuant to a strict doctrinal analysis that is contrary to the letter and spirit of the Affordable Care Act. In fact, as set forth below, Narco Freedom's model provides actual benefits to health care programs through the reduction of recidivism by substance abuse treatment patients and greater coordination of care.

1. Access to Care

As an initial matter, the Government is not alleging any fraudulent conduct relating to the provision of clinical substance abuse treatment services in Narco Freedom's treatment-with-housing model. Moreover, the Government acknowledges, as it must, that Narco Freedom is providing housing that its clients desperately need. *See, e.g.*, Tr. 154:5-10 (T. Herzog, acknowledging that "[t]here's a dearth of housing services available for this population."); Tr. 125:10–126:1 (R. Kent, acknowledging homelessness or lack of stable housing can lead to multiple health risks, dying younger, less access to patient care). *See also* OASAS Statewide

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"remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs ... .").

Comprehensive Plan 2013-2017 at 25 ("Forty three counties identified housing as a priority for the chemical dependence service system, with counties designating it as a top priority."), available at http://www.oasas.ny.gov/pio/commissioner/documents/5YrPlan2013-2017.pdf.[2]

At hearing, ample evidence was presented that Narco Freedom's model of treatment with housing promotes access to care in a way that is good for patients and for taxpayer funded substance abuse programs. Testimony by expert witness Dr. Edward Nunes confirms that treatment without housing is a waste. Tr. 58:2-10 ("it seems pretty clear from the evidence that homelessness is very bad for any effort to treat a substance use disorder. Homelessness is . . . extremely stressful. . . . Stress is one of the risk factors that makes addiction worse."); Tr. 62:7-12 ("addressing homelessness is an essential component of treating an individual that has a substance use disorder. In other words, if you have an individual sitting in your clinical office that has a substance use disorder and is homeless, you have to address the homelessness to have an expectation of a successful treatment plan.") Motivational incentives – such as housing provided here -- is an established model for treating addiction that is explicitly promoted by State regulations. *See* 14 NYCRR 822-2.6(c)(10) (providing that indicators that a program may be

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[2] Narco Freedom respectfully requests that the Court take judicial notice of this and subsequently-cited official guidance from OASAS. *See Saghlain v. DeVry Univ., Inc.*, 2007 U.S. Dist. LEXIS 97797, *9-10 n.9 (C.D.Cal. Dec. 10, 2007) ("Courts regularly take judicial notice of government agency websites and the information contained on them, treating official policies and records posted on the websites as public records."); *In re Willbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Penn. 2003) (taking judicial notice of published report of federal administrative agency and finding that publishing agency report on the internet "does not affect the Court's ability to take judicial notice of the contents of the report").

providing services that are not clinically justified do not include "established evidence-based practices that utilize incentives to affect patient behavior in the achievement of established treatment/recovery goals.") The conditions of the housing need not be ideal to be perfect; imperfect housing with less than ideal conditions can be valuable for treatment, especially when compared with the devastating effects of being homeless. Tr. 81:25-82:5 (E. Nunes).

Narco Freedom CEO Gerald Bethea testified that the decision to provide housing assistance was the product of Narco Freedom's experience that this was a serious problem for patients that was not being adequately addressed. Tr. 425:12-426:13. Just as Narco Freedom grew its services to include Mental Health in clinical services, Tr. 491:6-21 (J. Lerner), Narco Freedom also responded to the important patient need for basic shelter as part of its client-centered approach to treatment that has proven so successful, Tr. 425:12-426:13 (G. Bethea).

Indeed, the clinical success of Narco Freedom's integrated services approach remains unchallenged on the record before the Court, with data and statistical evidence showing defendant's treatment model to be exceptionally effective. Tr. 69:5-70:8 (E. Nunes). It is this record of successful, beneficial treatment (with housing and other services) that has spurred the growth of defendant's progress to its current level; not some speculative impact of a nefarious inducement outside the scope of established best practices for treatment.

Rather, housing was offered in an effort to further its patients' chance for successful completion of treatment programs. This client-centered and integrative approach is characteristic of Narco Freedom's approach to a full range of health-related services. Bethea Decl. ¶ 10-14; Tr. 428:21–429:1 (G. Bethea: "[W]e care so much about the treatment and the patients that a lot of times, we supplement those houses through our other programs, and they don't even have to

be substance abuse programs. They can be in our health homes, they can be our primary care, so it comes from an array of all of our services and from the pool of income that comes in.").

2. Low Risk of Harm

In comments issued in connection with a proposed regulation, the United States Department of Health and Human Services Office of Inspector General proposed to interpret the phrase "low meaning of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs" as meaning that "the remuneration: (1) Is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns." Those elements are fulfilled here.

(i) Narco Freedom's model is unlikely to interfere with, or skew, clinical decision-making

With a treatment-first model, there is no possibility of skewing clinical decision making because the housing decision is not made prior to the clinical intake and assessment. Tr. 435:15-436:18 (G. Bethea); Def. Ex. E (Intake form). Additionally, the Government has raised the issue of patient choice, implying that a patient being referred to Narco Freedom for treatment is somehow lacking the ability to make this choice versus other programs. It has failed, however, to acknowledge that it is the federal government itself, along with its state and local counterparts, that is failing to provide actual choice to substance abuse treatment patients – and others at risk of homelessness – when it comes to the provision of affordable housing.

In doing so, the Government has turned the issue of patient choice on its head; it accuses Narco Freedom of denying patient choice when in fact Narco Freedom is one of the few providers in this area that has stepped up and provided necessary housing to patients who otherwise would go without, at great loss to their chances at sobriety. The Government's

formulation of patient choice is illusory. It seeks to force Narco Freedom to open up its housing to other clinical providers who stand on the sidelines without addressing the housing needs of their own patients. *See, e.g.*, Tr. 265:2–24 (K. Greene: Bronx Lebanon Hospital takes only one or two clients into its residences from Rikers Island per year and none who can afford to pay only the $215 stipend provided by HRA). That is not a formula for incentivizing clinical providers to provide additional housing that addresses an established housing crisis for people seeking substance abuse services. Rather, it is a no-good-deed-goes-unpunished example of penalizing an innovative provider that dares to address an unmet need that should be rejected as a basis for the broad injunctive relief sought by defendants on a limited record.

Narco Freedom agrees that patients should have a right to choose a program that adequately addresses their housing needs in a way that they find to be acceptable. As a practical matter, other outpatient treatment providers have failed to step up and provide the adjunct housing that experts now agree is necessary for complete coordinated care for many patients, which is arguably no choice at all. *See, e.g.*, Tr. 173 (J. Salmon: Comprehensive Treatment Institute–Bronx unable to accommodate the housing needs of its outpatient clients); 265:2–24 (K. Greene, Bronx-Lebanon Hospital). Not surprisingly, patients in need of housing are either referred to or choose to come to Narco Freedom to obtain both their substance abuse treatment and housing; a choice of integrated care that should be promoted, not prohibited, under the amended definition of "remuneration." *See* Dept. of Health and Human Svcs. Office of Inspector Gen., 79 Fed. Reg. 59717, 59726 (proposed Oct. 3, 2014) (commenting on circumstances in which incentives to patients are acceptable). Accordingly, Narco Freedom's model is unlikely to interfere with, or skew, clinical decision-making.

(ii) Narco Freedom's model is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization

Narco Freedom's treatment-with-housing model also has a negative risk of financial harm to the Medicaid program or other federal health care programs. Freedom House residents are housed for only $215 per month. Kent Decl. ¶ 7. Other models receive payment of $1,156 per month, the Congregate Care Level II rate. Pl. Ex. P. That does not even reflect additional deficit funding that OASAS and other government agencies give to operators of housing initiatives, which results in an even higher cost to the government. Tr. 47:5-9 (R. Kent). OASAS also admitted that it could cost more when a client leaves Narco Freedom's clinical program to enroll in a different program, as that change triggers a renewal of the number of days before the APG Medicaid reimbursement rate is reduced. Tr. 128:23–129:14 (R. Kent).

Narco Freedom's model also provides substantial cost savings when improved treatment outcomes, including reduced recidivism, are factored in. Tr. 489:10-14.; OASAS "Homelessness & Housing" website, available at http://www.oasas.ny.gov/housing/homelessness.cfm ("living in a homeless situation often leads to coping with stress and crisis through greatly increased abuse of alcohol and other drugs"); OASAS Statewide Medicaid Re-Design Team (MRT) Permanent Supportive Housing (PSH) Initiative, RFP (Dec. 2012) at 2, available at http://www.oasas.ny.gov/procurements/documents/Statewide_MRT_PSH_RFP_FINAL_12-12-12.pdf ("lack of appropriate affordable housing may be major driver of unnecessary Medicaid spending; 10-15 percent of clients served through NYC's Managed Addiction Treatment Services (MATS) programs are homeless and over 60 percent are at risk of becoming homeless.") Alternatives to successful treatment enabled by housing cost much more than the $215 that Narco Freedom receives from HRA. *See, e.g.*, Def. Ex. AE, NYS OASAS Permanent Supportive Housing, at 10 (overnight stay in prison $165, in hospital $1,954).

Thus Narco Freedom's model actually *saves* federal health care dollars, and does not pose a heightened risk of harm.

(iii) Narco Freedom's model does not raise patient-safety or quality-of-care concerns

Although Narco Freedom questions the relevance of the Government's anecdotal attack on the conditions of the Freedom Homes; it does acknowledge that the independent living model of its housing resources is necessarily imperfect. Residents, all of whom have substance abuse problems, many of whom are emerging from a prison environment, and many of whom have substantial health and other problems, sometimes make bad choices, break the rules and exhibit bad behavior that can negatively affect others. It submits, however, that Narco Freedom is performing well at a tough job of providing basic housing resources to a challenging population with extremely little funding, while stretching its own limited medicated funs to the limit. A fair examination of the complete record reveals that the Government is holding Narco Freedom to an impossible and inappropriate standard with respect to its operations and conditions at its Freedom Houses. This standard fails to acknowledge that conditions complained of result from the independence that is required and appropriate for patients referred for outpatient services vs. residential services. Although the Government has attempted to characterize the Freedom Houses in a negative light, the challenges that Narco Freedom faces in that respect are common to all housing institutions in New York. Tr. 116:13-21 (R. Kent acknowledging drugs, bedbugs, rodents common in OASAS-certified community residence programs).

More importantly, the somewhat patronistic approach of the Government ignores the most important aspect of Narco Freedom's treatment success: its exceptional results and positive regulatory reviews, with no evidence of clinical problems or deficits. A site survey conducted by OASAS last month concluded that services were being provided uninterrupted and no Corrective

Action Plan was needed. Def. Ex. D; Tr. 106:17–107:14 (R. Kent). Moreover, Narco Freedom's regulatory record of exemplary annual reviews and highest certification levels show the true picture of a treatment model that works for patients. Tr. 427:22-428:10 (G. Bethea).

Even the sole Freedom House resident that the Government put on the witness stand admitted he went to housing court to attempt to *get back into* the same Freedom House he described in such dismal terms. Def. Ex. AA (Affidavit of R. Mack). The episode involving Mr. Mack only underscores the real context – that there is a severe housing shortage, and Narco Freedom is one of the few providers addressing that need for this underserved population; albeit with inadequate funding and all the challenges that come with housing substance abuse patients.

That conclusion is bolstered by the positive feedback that other Freedom House residents have volunteered that evidences the benefits that Narco Freedom provides to this vulnerable population in trying circumstances. For example, a former resident of a Freedom House released from Rikers Island stated that she "was proud to say that I had the opportunity to begin my [recovery] process here at Narco Freedom." Def. Ex. AH at 42-44. Similarly, another former resident of a Freedom House remarked that "It made me realize that I can do anything I set my mind to do. Through being here I learned how to live again. I found out my worth. I learned that I am capable of being a productive member of society." *Id.* at 185-86. A resident of Freedom House Six stated "I am grateful to Narco Freedom and all there [sic] help, referrals and advise. Today I have a commercial C license job." *Id.* at 218. While these sincere and heartfelt stories of hundreds of individuals who have succeeded at Narco Freedom are not quoted here at length, Narco Freedom respectfully submits that these submissions show that it has a track record for successful treatment that it has reason to defend and be proud of that is not properly reflected in the selective and anecdotal evidence offered by the Government.

Finally, Narco Freedom has made significant changes in recent months to strengthen its corporate governance and compliance capabilities. It has a new CEO with an extensive background and credentials in the area of substance abuse treatment, and its Board of Directors has appointed several new members with a deep and wide range of relevant experience. Tr. 409:20-413:1 (G. Bethea credentials and experience). These changes demonstrate Narco Freedom's commitment to addressing, in good faith, the concerns that the Government has raised. The new management at Narco Freedom is committed to a culture of continual improvement of services and conditions for its clients, including Freedom House residents.[3]

Because Narco Freedom's model poses a low risk of harm to patients, especially compared to the alternative of homelessness, Tr. 81:25-82:5 (E. Nunes), it is not "remuneration" and not an "inducement" under the AKS.

3. State law parallels the federal statutory exception

Not surprisingly, state law comports with the common-sense amendment to the federal definition of remuneration. Title 14 of the OASAS regulations – 822-2.6 ("Excessive provision of services") – provides that

> "(c) Indicators that a program may be providing services that are not clinically justified include, but are not limited to, evidence that the program has engaged in one or more of the following practices:
>
> . . .
>
> (10) provides financial or other incentives to patients and/or staff that promote increased services regardless of the actual needs of patients. ***This does not include established evidence-based***

[3] We note that although the Government has mentioned the prospect of a subsequent motion receivership, it has not asked for that relief at this time. Accordingly, a formal assessment of Narco Freedom's past or current corporate governance is not necessary to the determination of the instant motion.

> ***practices that utilize incentives to affect patient behavior in the achievement of established treatment/recovery goals.***"

14 NYCRR 822-2.6(c)(10) (emphasis added).

At hearing it was clearly established that Narco Freedom's provision of housing as an adjunct to substance abuse treatment is an adjunct, clinically effective, evidence-based practice that utilizes incentives to "affect patient behavior in the achievement of established treatment and recovery goals." Tr. 72:9-17 (E. Nunes). This convergence between state and federal guidance is not surprising because it derives from the new understanding that treatment yields better outcomes when it is coordinated. Tr. 72:1-22 (E. Nunes). Accordingly, because Narco Freedom's model does poses a low risk of harm to patients and to federal health care programs (and is an "established evidence-based practices that utilize incentives to affect patient behavior in the achievement of established treatment/recovery goals" in accordance with OASAS regulations), it is not "remuneration" and not an "inducement" under the AKS.

C. The One Purpose Rule is Not the Law in the Second Circuit and Would Not Apply Here Even If It Were

Narco Freedom submits that the "one purpose test" that some courts in other Circuits have adopted does not and should not apply in this case, and even if it did, Narco Freedom's model should still be deemed lawful.

1. The One Purpose Rule is Not the Law in the Second Circuit

Even if the provision of housing in these circumstances were deemed to be remuneration, the Government's argument would still fail because the One Purpose Rule is not the law in this Circuit. The Government has cited only two cases for that proposition. An examination of those cases, however, reveals that neither supports that proposition.

United States ex rel. Kester v. Novartis Pharms. Corp., 2014 U.S. Dist. LEXIS 74461 (S.D.N.Y. May 29, 2014) arose on a motion to dismiss claims under AKS and False Claims Act. The court, in reviewing the Government's position, cited a 1994 OIG Special Alert for the proposition that "If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated." The court noted that the defendant "does not dispute that such activities constitute AKS violations." Notably, therefore, the court did not even adjudicate the issue; it simply cited that point agreed upon by the parties and moved on to the actual dispute – whether falsity under the False Claims Act can be predicated on AKS violations.

While the Second Circuit recently affirmed a District Court's jury instructions consistent with the "one purpose test," that decision also upheld the further requirement that the prosecution prove "the remuneration was offered or paid as a quid pro quo in return for the referring of the patient." *United States v. Krikheli*, Nos. 11-2865-CR (L), 11-2869-CR (CON), 461 F. App'x 7, 11 (2d Cir. Feb. 2, 2012) This further quid pro quo requirement adds an element of significance to the intended purpose which more closely aligns with the "primary purpose test" and would act to limit the breadth of the "one purpose test," if adopted in this Circuit. Narco Freedom respectfully submits that a test similar to the "primary purpose test" is the appropriate test for this district and circuit, particularly in this very complicated case and dynamic regulatory environment.

Accordingly, contrary to the Government's assertion, the Second Circuit has *not* adopted the one purpose test. The more appropriate standard for Anti-Kickback Statute is the "primary purpose test," which holds that the "primary purpose" must be improper in order to obtain a conviction under the Anti-Kickback Statute. *United States v. Bay State Ambulance and Hosp.*

Rental Serv., Inc., . It is not a violation if the improper purpose behind the payments was an "incidental or minor one." *Id.* at 29-30. In affirming the decision, the court specifically discussed, but chose not to adopt, the *Greber* test. Narco Freedom respectfully submits that this Court should do the same, especially in light of the ACA amendment that facilitates the integration of services and supportive resources.

2. The Purpose of the Freedom Houses is to Improve Treatment

Regardless of the test adopted and applied in this case, Defendant Narco Freedom's housing program is not intended to improperly induce Medicaid referrals in a way that is violative of the AKS. The Government conflates Narco Freedom's legitimate interest in providing an integrated, client-centered treatment model with some improper nefarious intent to defraud. To establish an improper "purpose" to defraud, the Government must show more than a desire to provide care and services that are established to be an important, aspect and clinically desirable treatment model. *See Bay State Ambulance*, 874 F.2d at 29-30 (upholding District Court's jury instruction that the "primary purpose" must be improper). Here, however, the Government relies upon equivocal and conflicting statements attributed to Narco Freedom's former CEO[4] which are completely consistent with Defendant's mission and legitimate clinical purpose to serve clients in an integrated client centric approach that is the cornerstone of modern modalities.

Accepting that housing is an integral aspect of a patient's plan for recovery (a point Narco Freedom believes is well-established and uncontradicted) it is also a critical aspect of New York's mandated approach to delivery of substance abuse services, which includes consideration

[4] Alan Brand communicated by counsel that he would have invoked his Fifth Amendment rights had he been called to testify. Tr. 17:10-14.

and resolution of housing issues. The Government's insinuation that defendant's decision to stretch its scarce Medicaid dollars to help patients afford basic, temporary housing is borne of a "profit" motive is belied by the record and by the fact that Narco Freedom is a not-for-profit charitable corporation that derives no "profit" from its operations. Rather, revenues generated go toward program expenses and expansion and improvement of its programs.

The mere fact that the provision of housing may have made Narco Freedom's treatment programs more effective, successful and desirable to patients and referral resources, is insufficient to establish an Anti-Kickback Statute violation here. *See Bay State Ambulance*, 874 F.2d at 29-30 (no AKS violation where "primary purpose" proper). Even the Government's own witnesses established that the purpose of establishing the sober homes was to improve clinical outcomes in a way that made Narco Freedom's treatment programs successful. Tr. 315:6-316:2 (J. Deutchmann stating that "by giving someone a place to live, you're ensuring -- you have a higher percentage that they're going to go to treatment, which is going to help them long term" and "[w]hen [patients] lived in a house, there are rules and regulations, so there are curfews, and it was better for the client, because everyone who lived in the house was trying to live a sober-free life").

Defendants submit that an interpretation of the AKS that prohibits such efforts to improve clinical results of treatment models obviously contravenes public policy that favors better treatment. Moreover, the marketing of the entire clinical-with-housing package is not a kickback per se. Government witness Donna DiCicco confirmed that she conducts outreach for Narco Freedom's services that have housing as a component, but that is simply a statement of her "outreach" function within the organization, which the Government improperly takes out of context as evidence of some nefarious profit motive. Tr. 343:25-344:8 ("[T]he outpatient

treatment was first because they had to have a substance abuse history in order to want to go to Narco Freedom. I wasn't presenting it as housing because that's not what it was."). This practice comports with guidance on marketing provided by OASAS, which in its Clinical Guidance states that "[k]nowledge, information, and data, from and about individuals and groups, should be transformed into clinical standards, service approaches, **and marketing programs** that match the communities and people living in them. Doing so increases the quality and appropriateness of health care and improves health outcomes." OASAS Clinical Guidance (Oct. 2012) at 8, available at http://www.oasas.ny.gov/treatment/documents/ClinicalGuidance-Final.pdf. That Narco Freedom was always concerned about the need to fully utilize its scarce housing resources by "keeping the houses full" is only evidence of good utilization of scarce resources rather than an indication of an improper motive to induce.[5]

The Government therefore has failed in its burden to establish that the purpose of Narco Freedom's provision of housing is an illegal inducement under the AKS.

II. THE GOVERNMENT HAS FAILED TO SHOW IRREPARABLE HARM ABSENT A PRELIMINARY INJUNCTION

The Government also has not met its burden of showing irreparable harm without an injunction because the continuation of Narco Freedom's treatment-with-housing model poses a low risk of harm – and indeed actual benefits – to its clients and to federal housing programs. No experts analyzing utilization; no evidence of excessive services, only the reality that patients are getting access to care they are entitled to and need with the housing that is a necessary and supportive component of care.

[5] Upon information and belief, OASAS and the New York State Medicaid Program have penalized inpatient treatment facilities for not maintaining a sufficiently high occupancy rate.

As set forth above, Narco Freedom's model actually provides benefits, not harm, to the government health care programs. Indeed, the Government has neither shown nor calculated how or to what extent beneficiaries are receiving care that they do not need, and it has failed to show any fraud (past or ongoing) that adversely impacts the federal health care programs.

III. THE BALANCE OF THE EQUITIES LIE WITH NARCO FREEDOM

The equities weigh heavily ***against*** granting the Government's proposed injunction.[6] The impact of the broad injunction that the Government is now seeking would likely force the closure of Narco Freedom's Freedom Houses and would likely have a cascade effect on other housing providers using the "sober home" model. Tr. 429:15-24 (G. Bethea).

In deciding whether to grant an injunction, the Court should assess all considerations of fairness, including the potential adverse effects of an injunction on the defendant and non-parties. *See Management Dynamics, Inc., supra.* In this case, the broad injunction sought by the Government would destroy Narco Freedom's treatment model, likely require Narco Freedom to close its Freedom Houses, leave Narco Freedom's patients in limbo, and likely have a wide-reaching impact on other sober living and holistic treatment programs.

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[6] Aside from the substantive arguments going to the equities, there is a procedural element as well. Narco Freedom requested a stay of these proceedings in light of the criminal indictment against Narco Freedom's former CEO and sole member, Alan Brand. The Court denied that motion. The Government devoted significant portions of its opening and closing arguments at hearing making assertions and suggesting inferences concerning purported acts and omissions of Mr. Brand, who had communicated by counsel that he would have invoked his Fifth Amendment rights had he been called to testify. Tr. 17:10-14.

A. The Government's proposed relief would displace existing State regulatory schemes that effectively depend up on the existence of residential resources

1. Narco Freedom's Treatment-With-Housing Model fills a gap and cannot be replaced by other existing residential treatment models

(i). State Regulatory Backdrop

There are multiple levels of state regulation that apply to Narco Freedom's operation of its Freedom Houses, consistent with this area that has been traditionally regulated by the states. For example, the Department of Parole assesses patients and orders them to Narco Freedom for treatment and housing pursuant to state laws, rules and regulations governing parolees. Tr. 148:6-10 (T. Herzog). Medicaid pays a $215 per month stipend that is known to be insufficient to support any unsubsidized housing options, leaving only the city shelter system representing a wholly undesirable option that even State Parole officials even deem unacceptable. *See* Def. Ex. T at 3 (DOCCS RFP stating: "The Contractor will assist in community transitioning. **Shelter placement shall not be considered a desirable placement.**") (emphasis in original). In tandem, OASAS requires outpatient providers like Narco Freedom to address housing needs as part of its treatment planning, but does not provide a licensed service for Narco Freedom-level patients, who simply need outpatient treatment but have temporary housing needs. It is well known, however, that this situation creates a substantial gap in housing resources for Medicaid participants in outpatient treatment programs. At the legislative level, however legislation is pending for certain regions, specifically regulating three-quarter homes in a way that requires them to be associated with a treatment program. Def. Ex. V. Notwithstanding these pending legislative efforts, OASAS does not currently oversee three-quarter homes where no treatment is provided, even as it finances and endorses licensed versions of three-quarter housing for more acute conditions that could likewise be considered "inducement" in the broadest terms, and could

be negatively impacted by the relief and precedent sought by the Government. Lastly and more locally, the buildings themselves are subject to the regulatory authority of the various municipalities where they are located. It is difficult to conceive of a more inconsistent maze of state regulations that could pertain to the housing issues presented to this Court, yet it is this backdrop of confusion and inconsistencies that providers like Narco Freedom must navigate in meeting the needs of patients.

(ii). Narco Freedom's Model meets an unmet need not addressed by OASAS-certified providers

Narco Freedom provides housing to people enrolled in its outpatient substance abuse treatment program who would simply not be eligible for other forms of housing proposed by the Government. It is undisputed that a significant portion of Narco Freedom's outpatient substance abuse treatment clients are referred from prison or other inpatient programs. Tr. 160:5-8 (T. Herzog). The Government's own witnesses admitted that this gap exists where Medicaid recipients qualify only for outpatient substance abuse treatment programs that do not include housing resources, but do not qualify for a licensed residence program that would provide both housing and treatment pursuant to State criteria. Tr. 171:11-14, 172:12-17 (J. Salmon).

The "gap" served by Narco Freedom is best explained by an analysis of the OASAS "Level of Care" hierarchy, which funnels patients to the lowest appropriate category of level of care based upon established criteria. Narco Freedom has provided ample evidence that this gap exists between licensed facilities that provide treatment in-house (at least in part) and services approved strictly on a far less expensive outpatient treatment basis.

In its quest to understate the potential negative impact of its proposed banning of three-quarter home models like Narco Freedom, the Government has referenced, through witnesses, two types of chemical dependence residential services as viable "funded" alternatives that could

theoretically meet the housing needs of the Narco Freedom patient population: Community Residential Services ("CRS") and Supportive Living Services ("SLS"). Kent. Decl. ¶¶ 3-7. The implication of this evidence is that there is no need for programs that provide unlicensed housing resources. However, Narco Freedom has shown how those levels of care have threshold assessment criteria that most Narco Freedom outpatient clients simply *cannot meet*, thus creating a large "gap" for patients who qualify for outpatient treatment but not housing.

The CRS model, for example, is designed for patients who have been determined, clinically, to be in need of "24/7 support" and "a structured therapeutic environment," typically coming out of a long-term or intensive residential treatment programs. 14 N.Y.C.R.R. 819(9)(b)(1); Tr. 44:17-19 (R. Kent); Planning Resources, OASAS Website, available at http://www.oasas.ny.gov/hps/state/CD_descriptions.cfm#CD. At the lower end of the "housed" treatment spectrum is the SLS model, which does not provide 24/7 clinical structure or supervision, is not widely funded or available, and is (14 N.Y.C.R.R. 819(10)(a)(2), 819(10)(b).) designated by regulation only "for individuals who have completed another course of treatment." 14 N.Y.C.R.R. 819.2(a)(3); Tr. 113:6-12 (R. Kent); *see generally* OASAS Planning Resources, available at http://www.oasas.ny.gov/hps/state/CD_descriptions.cfm.

Residents referred to Narco Freedom's outpatient program Freedom House in contrast do not, by definition, meet criteria that would establish a need for clinical services in a "housed" treatment program that is far more expensive than outpatient treatment and reserved for individuals requiring a higher level of care. *See* Tr. 423:21 – 424:1 (G. Bethea, level of care for Narco Freedom's outpatient clients is "totally different" from those eligible for community residence). Indeed, the patient group referred to Narco Freedom has almost always been evaluated and assessed by other providers, or by DOCS or Parole staff, to be eligible for this

lower level of outpatient care which includes no provision for housing other than the $215 per month stipend provided by HRA. As explained by Narco Freedom CEO Gerald Bethea, "residential" patients need a higher level of care, meaning more intensity of services. Tr. 418:23-419:15 (G. Bethea). As expert witness Dr. Janet Lerner likewise testified, people deemed eligible for inpatient residences "can't make it with just having housing probably do need to go to that level of care." Tr. 494:5-10.

In contrast, however, lies the general "outpatient" service population referred to Narco Freedom consisting of "people who are doing pretty well coming out of prison, coming into our programs and staying, and working it out just living in the [Freedom House] residences and learning a whole lot of things they never knew they needed to know." Tr. 494:5-10 (J. Lerner). The Government has failed to show how or why this gap of referrals to outpatient treatment programs, without housing, would be housed if 3/4 home referrals were deemed improper.

Critically, another important difference between the high-level-of-care inpatient residences and the Freedom House model is cost, a driving factor for the State's Medicaid program. The cost to the government for a resident at a Freedom House is only $215 per month, paid by the New York City Human Resources Administration ("HRA"). Kent Decl. ¶ 7. In contrast, it is established that both the CRS and SLS models (proffered by the Government as viable alternatives to independent thre-quarter homes) cost the government more than four times as much -- $1,156 per month in New York City and environs pursuant to the Congregate Care Level 2 rate. Pl. Ex. P; Kent Decl. ¶ 7 ("For both the community residential services and supportive living services programs . . . , the funding levels provided by [HRA] are significantly higher than the $215 per month shelter allowance provided to three-quarter houses.")

It is this stark cost differential that significantly limits the availability of housing that can be provided per a given funding level. Even OASAS General Counsel Robert Kent admitted that "[t]here's not funding for [the conversion of] every house." Tr. 117:3. Remarkably, to the extent that OASAS has any inkling of a plan to replace the housing currently being provided under the three-quarter house outpatient model, Mr. Kent acknowledged that this long-term solution would require pursuit of additional funding from *the patients themselves* – the same patients who are established to be so impoverished that they qualify for Medicaid under the applicable poverty standards. Tr. 118:16-17 ("Well, there's nothing that would prevent the individual from contributing for the cost themselves.")

Mr. Kent further admitted that his agency had no plan for this group of patients if Narco Freedom became unsustainable, nor had OASAS conducted any study regarding the impact of the loss of sober homes such as the Freedom Houses. Tr. 109:18-24 (R. Kent) Instead, he offered only a speculative, unsubstantiated plan for taking over Narco Freedom with the vague suggestion that something could be figured out. Tr. 110:2-7. Indeed, virtually every "industry" witness produced admitted that they had no information regarding the scope of the housing gap that is filled through three-quarter housing. Tr. 108:17-19 (R. Kent).

Narco Freedom submits that the utter failure of the Government (State and Federal) to affirmatively demonstrate how the vital housing resources of Narco Freedom would be replaced is a fundamental flaw in the Government's case. Considering the drastic and immediate relief sought which could have a potentially immediate and irreparable impact on patients who currently have a roof over their head, this contradictory, equivocal and unconvincing evidence of adequate existing alternatives warrants this Court's careful scrutiny of the Government's sweeping request for immediate injunctive relief.

The connection of Narco Freedom's treatment program with residence in a Freedom House is a vital component of treatment for many patients. The model is supported by scientific research and is proven by the results obtained by Narco Freedom. Tr. 69:19-70:8 (Dr. Nunes discussing Narco Freedom's retention rates' as documented by Bronx Re-Entry Task Force exceeding national averages). By offering residency in a Freedom House to qualified individuals who are enrolled in Narco Freedom's treatment programs, Narco Freedom is able to ensure that the patients are following through with their treatment, that already at-risk individuals are properly monitored, and that basic rules and structures are in place to prevent, or at least limit, the patients from engaging in negative conduct. Bethea Decl. ¶ 15.

2. Granting the Preliminary Injunction Would Destroy the Ability of Narco Freedom – and Other Sober Home Operators – to Serve This Vulnerable Client Base.

The injunction sought by the Government would destroy that holistic treatment program. By seeking to force Narco Freedom to eliminate the treatment/housing connection, the Government would transform the Freedom Houses from an effective adjunct to the treatment of addiction to just another place for at-risk individuals to congregate. Lerner Rep. ¶ 32.

Moreover, and perhaps most importantly, without the ability to properly monitor the individuals residing at the Freedom Houses, Narco Freedom could not safely or effectively operate the Freedom Houses and would, most likely, be forced to close them down. Not only would this obviously eliminate the availability of housing for numerous patients, but it would also eviscerate the core of the Narco Freedom treatment program. Bethea Decl. ¶ 19-20.

Forcing Narco Freedom to eliminate its treatment plus housing model is not medically responsible or supportable. The Government has presented no scientific evidence in support of its motion. Narco Freedom has provided abundant evidence, factual and medical, showing that

its program provides the best possible means for patients to have a successful outcome. Nunes Rep. ¶ 19-24; Lerner Rep. ¶ 12-23.

Additionally, as set forth above, the Government's suggestion that Narco Freedom should move to a Community Residential Services model or some other model is not tenable. *See* Lerner Rep. ¶ 35-36; Tr. 423:21–424:1; Tr. 418:23-419:15 (G. Bethea); Tr. 494:5-10 (J. Lerner). In fact, it is the Government's proposal that would jeopardize coordination of care by forcing other providers into the middle of Narco Freedom's relationship with its clients, with ensuing challenges of logistics, communications and confidentiality. Tr. 430:19-431:3 (G. Bethea).

The injunction sought by the Government would also threaten the viability of other sober living and holistic treatment programs. *See* Tr. at 109:9-10 (R. Kent acknowledging hundreds of other sober homes in New York City alone) If the Government is able to dismantle the Narco Freedom treatment plus housing model, similar programs throughout the country would be on notice and in jeopardy of suffering the same fate. Fear of the Government could reasonably cause valuable holistic treatment programs to either shut down entirely or modify their programs in a manner that is not as effective and beneficial for the patients.

Another equitable factor weighing against the issuance of a preliminary injunction is that such a determination could be wielded by public and private litigants under the False Claims Act and or other similar statutes to attack similar housing programs. The Government has asserted that it may pursue claims under the False Claims Act. Mem. of Law, ECF No. 10 n.6. Such a broad attack could cause other providers to shy away from providing housing services at a time when that adjunct to care is in short supply.

3. The Government seeks to use the fraud injunction statute for an improper purpose.

The Government is essentially proposing a corporate hijacking, which is outside the scope of the authority granted by the fraud injunction statute. *See United States v. De Maria Cacho-Bonilla*, 206 F. Supp. 2d 204, 208 (P.R. 2002) ("Since the fraud injunction statute does not authorize the reorganization of a private corporation, the government's position in seeking such remedy was not substantially justified.").

This attempt by the Government is particularly inequitable where the Government has implicitly endorsed the same type of subsidized housing in OASAS licensed residences that it labels a kickback when provided by Narco Freedom. In OASAS-certified facilities housing is provided at less than fair-market cost, just as in the Freedom Houses. However, OASAS makes up the difference through deficit funding in its certified housing. Tr. 47:5-9 (R. Kent). It makes no sense from a public policy perspective that Narco Freedom is being singled out because it absorbs the deficits itself rather than passing these costs on to the taxpayers.

4. The Government has shown no harm in the absence of its requested preliminary injunction.

On the other side of the ledger, there is an utter lack of any evidence to document or quantify any purported financial harm to the government. There is quite simply a complete absence of any evidence showing how this alleged violation of the code of its interpretation of the kickback statute resulted in overutilization of services in any way.

Balancing this outcome against weight of alleged harm to the government during the pendency of this matter, hard to justify injunctive relief that would give the government all that it seeks before discovery even begins. The solution offered by the plaintiff would leave defendant in the position of financing the cost of temporary housing for patients of other providers who would benefit financially from the treatment provided while avoiding the cost of

the housing that Narco Freedom currently provides to its patients. That proposal puts an extreme burden on the defendant.

5. Narco Freedom has sought to address the Government's concerns – and continues to do so.

The Government has refused Narco Freedom's unilateral efforts to address in practical ways the concerns at the heart of the Government's legal arguments which we set forth in the proposed order. A week and a half ago Narco Freedom submitted a proposed preliminary injunction that contained an innovative provision designed to solve what appears to be the primary conceptual problem for the Government. Specifically, the proposed order would allow Narco Freedom to condition residence in a Freedom House upon enrollment in Narco Freedom's outpatient program or in any other OASAS-certified outpatient program that agrees to contribute toward the patient's housing at the same per patient rate as Narco Freedom. ECF Doc. Nos. 67, 67-1. Narco Freedom is continuing to communicate with the Government in good faith and is scheduled to meet with the Government and other stakeholders next week to discuss potential models that will address the concerns of all parties and stakeholders.

In sum, the negative impact of granting the Government's injunction is substantial. It would significantly damage Narco Freedom's entire treatment program and thereby directly impact the patients enrolled in Narco Freedom's program, which, ultimately, would impact the public at large. On the other hand, denying the injunction and maintaining the *status quo* while this matter is pending a full and final determination carries little risk and negligible negative impact on any party, Narco Freedom's patients, and the public at large. Thus, in consideration of fundamental fairness and the potential impact of an injunction, the Court should deny the Government's application for a preliminary injunction.

CONCLUSION

Accordingly, for all the reasons stated above it is respectfully submitted that the Court deny the Government's application for a Preliminary Injunction, and if the Court deems any relief necessary, we ask that the Court consider a remedy consistent with the proposed preliminary injunction order submitted by Defendant.

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HISCOCK & BARCLAY, LLP

By: /s/ Linda J. Clark
Linda J. Clark
Joseph A. Murphy

Attorneys for Defendant
Narco Freedom, Inc.
80 State Street
Albany, New York 12207
Telephone: (518) 429-4241
lclark@hblaw.com
jmurphy@hblaw.com